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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/799,299

03/12/2004

Gerald Horn

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07/13/2011

EXAMINER

HAND, MELANIE JO

ART UNIT

PAPER NUMBER

3761

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/799,299	Applicant(s) HORN, GERALD	
	Examiner MELANIE HAND	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 May 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. The affidavit under 37 CFR 1.132 filed May 6, 2011 is insufficient to overcome the rejection of claim 33 based upon the Galin reference as set forth in the last Office action because: The applicant's remarks appear to intend the affidavit to overcome the rejection of claim 33, which is rejected under 35 U.S.C. 102 (b), the rejection thus being a "statutory bar", and thus cannot be overcome by an affidavit under 35 U.S.C. 132. However, as a courtesy, the examiner will address the content of the affidavit. The affidavit refer(s) only to the system described in the above referenced application and not to the individual claims of the application. Thus, there is no showing that the objective evidence of nonobviousness is commensurate in scope with the claims. See MPEP § 716. The affiant refers to Table 1 of the specification as evidence that experiments were conducted that show that the claimed phentolamine-based formulation yields enhanced pupil reduction effect compared to "other types of alpha-1 antagonist-based formulations". First, Table 1 of the specification shows enhanced pupil reduction effect at one specific concentration of phentolamine versus several alpha-1 antagonists, none of which are the antagonist mentioned by the affiant as allegedly being the only working example disclosed by Galin. Second, Galin discloses a phentolamine-based formulation having an amount of phentolamine that meets the definition of "therapeutically effective amount" as disclosed by the applicant/affiant. Thus it is unclear how the working example disclosed by Galin employing thymoxamine is relevant. Even if it were, thymoaxmine was not compared to phentolamine in Table 1 of the specification, so the applicant has not established that thymoxamine is inferior to phentolamine in pupil reduction effect and thus

unable to meet the claim limitations. The affiant is finally referred to claim 1 of Galin wherein phentolamine in a concentration range overlapping that recited in claim 34 is explicitly recited.

Response to Arguments

2. Applicant's arguments filed May 6, 2011 have been fully considered but they are not persuasive. The remarks in their entirety are a reiteration of remarks presented in the above-mentioned affidavit addressed above in detail as being insufficient to overcome the rejection of claims 33-35 under 35 U.S.C. 102 and claim 36 under 35 U.S.C. 103.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 33-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Galin (U.S. Patent No. 4,443,441).

With respect to **claim 33**: Galin discloses an ophthalmic formulation in aqueous solution for topical administration, comprising: a sterile aqueous carrier (Col. 2, line 11); and a pharmaceutically active compound consisting essentially of phentolamine in a therapeutically effective amount, namely 0.1 -1 % by weight composition with a water solvent, to contract a pupil of a human patient's eye in dim light so that the pupil is effectively reduced to improve

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vision in dim light and further to minimize eye redness.

With respect to **claim 34**: The pharmaceutically active compound disclosed by Galin is present in an amount of 0.1-1% by weight of the ophthalmic solution. As the solvent and major component of the solution is water, and one gram is present in every one cubic centimeter, the active agent is present in an amount of 0.001-0.01 g (1-10 mg) per milligram of solvent or more. Since there are other components in the solution, the weight percent in water of the agent will be greater than the weight percent of agent in solution. This overlaps the claimed range of from about 0.01 milligrams per cubic centimeter of solvent to about 50 milligrams per cubic centimeter of solvent.

With respect to **claim 35**: The sterile aqueous carrier disclosed by Galin comprises purified water, sodium acetate, boric acid and phenylmercuric nitrate and thus it is the examiner's position that the sterile carrier meets the limitation of an ophthalmic artificial tear solution. (Col. 2, lines 3-12)

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Galin ('441).

With respect to **claim 36**: It is the examiner's position that since Galin discloses an active agent identical to some disclosed by applicant (e.g. phentolamine), though Galin does not explicitly disclose that the pupil is effectively reduced by 1.0 mm or more, one of ordinary skill in the art can reasonably expect that the solution disclosed by Galin will accomplish this result, rendering claim 36 unpatentable.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE HAND whose telephone number is (571)272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie J Hand/
Primary Examiner, Art Unit 3761